FOOD SUPPLEMENTS

ADMINISTRATIVE PROCEDURE for Compliance with Reporting Duty

(14. 12. 2021)

I. INTRODUCTION

from 1. 1. 2015

In accordance with Section 3d, par. 1, subpar. b), Reporting Duty of Food Business Operator, of Act No. 110/1997 Coll., on food and tobacco products and on the amendment and supplementation of some related acts, as amended, (hereinafter the "Food Act"), a food business operator that produces or markets food supplements shall **before they are first marketed, send the Ministry of Agriculture a Czech text of the designation, including mandatory information that will be specified on the product packaging.**

Food supplements are a special category of food. A food supplement is defined in Section 2, par. g), of the Food Act as *"a food whose purpose is to supplement ordinary nutrition and that is a concentrated source of vitamins and mineral substances or other substances with a nutritional or physiological effect contained in the food independently or in a combination designated for direct consumption in small measured quantities."* In accordance with Section 11, par. (1), subpar. f) of the Food Act, food supplements can be marketed only in packaging, and in accordance with Section 4, par. 1, of Decree No. 58/2018 Coll. on food supplements and the composition of foodstuffs, as amended, food supplements are used in the form of capsules, lozenges, tablets, pills and other similar forms, as well as in the form of granules, as liquid in ampoules, dropper bottles and other similar forms of liquid or bulk products intended for intake in small measured quantities and are marketed as such. This is a transposition of par. a) of Article 2 of Directive of the European Parliament and of the Council 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

II. LEGAL BASIS

The following legislation applies to the production, composition, marking, handling and marketing of food supplements:

- Act No. 110/1997 Coll., on food and tobacco products and on the amendment and supplementation of some related acts, as amended;

- Decree No. 58/2018 Coll. on food supplements and the composition of foodstuffs, as amended, (transposition of Directive of the European Parliament and of the Council 2002/46/EC on the approximation of the laws of the Member States relating to food supplements);

- Decree No. 417/2016 Coll., on certain methods of labelling foodstuffs, as amended;

- Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended;

- Regulation (EC) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as amended;

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, as amended;

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods, as amended;

    - Nutrition claims (NC) are specified in lists of NC: Annex to Regulation of the European Parliament and of the Council (EU) No 1924/2006, Commission Regulation (EU) No 116/2010, No. 1047/2012;

    - Health claims (HC) are progressively approved and are published in lists of approved HC: Commission Regulation (EU) No 432/2012 and also lists in Commission Regulations (EU): No. 980/2009, 983/2009, 1024/2009, 384/2010, 957/2010, 440/2011, 665/2011, 1160/2011, 1048/2012, 851/2013, 1018/2013, 40/2014, 1135/2014;

- Commission Regulation (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements;

- Regulation (EC) No 2283/2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, as amended;

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, as amended;

    - Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (the regulation has been applied from 1 June 2013);

    - Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.

It is important to keep an eye on trends in legislation and the valid text of regulations, both in the Czech Republic and in the EU and bring the marking of products into compliance with valid rules. The aforementioned list of legislation is only informative.

III. ADMINISTRATIVE PROCEDURE for Compliance with Reporting Duty

1) A food business operator who markets a food supplement will send a notification on the marketing of the food supplement to the Ministry of Agriculture in the form **of the submission of the text for the marking of the product, including the mandatory information about the food that will be specified on the packaging for the food in Czech**, either electronic or in paper form:

Electronically (preffered way of Compliacne with Reporting Duty):

Food notification system (SOP): https://eagri.cz/ssl/app/Sop/Gui/

Alternatively, it is possible to use the following methods of Compliacne with Reporting Duty:

Electronic address: podatelna@mze.cz
ID DS: yphaax8
Maximum size of data message: 10 MB
Notes: Notification – Food Supplement

In writing:

Ministry of Agriculture
Food Production Department
Těšnov 17
117 05 Prague 1
Notes: Notification – Food Supplement

2) The food business operator who notifies of the marketing of a food supplement is responsible for the correctness and content of a notification.

3) On the day notification is sent the food business operator discharges its duty in accordance with Section 3d, par. 1, subpar. b), of Act No. 110/1997 Coll., on food and tobacco products, as amended. In the event all the legislative requirements are met, a food supplement can be marketed on the day notification is sent on the marketing of the food supplement to the Ministry of Agriculture. **The food business operator marketing a food supplement is responsible for complying with the requirements of legislation, including product safety and marking.**

4) The Ministry of Agriculture **does not send out confirmation of compliance with the reporting duty**.

5) **The same administrative procedure is applied in the case of Compliance with Reporting Duty for foods to which are added vitamins, minerals or other substances with a nutritional or physiological effect listed in Parts B and C of Annex III of Regulation (EC) No. 1925 / 2006** in accordance with Section 3d par. 1 subpar. a) Reporting Duty of the Food Act.